REMARKS/ ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

Disposition of Claims

Claims 53-72 are pending in this application. Claims 1, 3, and 4 have been cancelled.

Rejections under 35 U.S.C. §112

Claims 1, 3, and 4 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claims 1, 3, and 4 have been cancelled. Accordingly, this rejection is moot.

Rejections under 35 U.S.C. §103

Claims 1, 3, and 4 were rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,952,004 (Rudnic et al.) in view of U.S. Patent No. 4,692,326 (Eckenhoff et al. or '326 patent) or U.S. Patent No. 4,800,056 (Eckenhoff et al. or '056 patent). Claims 1, 3, and 4 have been cancelled. Accordingly, this rejection is moot.

New Claims

Claims 53-72 are newly added.

Antiviral drugs such as protease inhibitors such as anti-HIV drugs have a potential of inducing drug resistance, particularly when patients inadvertently miss the medication due to poor compliance. This poor compliance leads to so-called "drug holiday," during which the concentration of the antiviral drug is below the therapeutic level. Antiviral drugs such as protease inhibitors are solids with limited absorption, poor aqueous solubility, and low availability. They are prone to drug aggregation due to hydration inside conventional matrix and oral delivery systems. This drug aggregation could lead to erratic release profile. Also, some antiviral drugs like anti-HIV drugs require high doses.

Claim 53 recites a sustained release oral dosage form that can increase patient's compliance, thereby minimizing the potential of drug resistance. Claim 53 recites a sustained release oral dosage form comprising a liquid antiviral drug composition comprising an antiviral drug solubilized in a solvent consisting of a surfactant. The sustained release dosage form recited in claim 53 provides benefits in terms of drug loading. For example, it has surprisingly been found that nelfinavir, a protease inhibitor, could be solubilized in a surfactant by up to 60 wt%. The antiviral drug composition recited in claim 53 is also substantially free of in-situ drug aggregation and provides substantially improved drug bioavailability.

The formulations disclosed in Rudnic et al. are emulsions. The emulsions comprise an oil phase, an aqueous phase, and optionally a surfactant or emulsifying agent, where the drug is dispersed in either the aqueous phase or the oil phase. In contrast, the liquid antiviral drug composition recited in claim 53 is an isotropic, homogeneous drug solution that does not include water. The antiviral drug is solubilized in a solvent consisting of a surfactant. The antiviral drug composition can disperse into an aqueous medium to form either micelle or emulsion in-situ, but only after the antiviral drug composition is released from the dosage form.

The '326 and '056 patents do not overcome the deficiency in Rudnic et al. because they do not teach an antiviral drug solubilized in a solvent consisting of a surfactant. Further the '326 and '056 patents do not teach a barrier layer between the antiviral drug composition and the expandable layer, as recited in claim 66, or between the capsule containing the antiviral drug composition and the expandable layer, as recited in claim 68.

Conclusion

Applicant believes that this paper is fully responsive to each and every ground of rejection cited by the Examiner in the Office Action dated March 23, 2004, and respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Adenike Adewuya

Adenike A. Adewuya
Reg. No. 42,254
Tel.: (281) 477-3450